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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,786	10/17/2003	Puranam Usha Sarma	41144F0071	1769

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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/686,786

Applicant(s)

SARMA ET AL.

Examiner

Angela Bertagna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/17/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group I, claims 1-4, in the reply filed on May 9, 2006, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5 and 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on May 9, 2006.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Priority*

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-

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filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/102,731, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claims 1-4 are not adequately supported by the prior-filed application 10/102,731, because the instant claims are directed to a method comprising amplification of exon IV of the human SP-A2 gene and determining the frequency of SNPs at positions 1649 and 1660, whereas the '731 application is directed to a method of amplifying the exon II region of the human SP-A2 gene and determining the frequency of SNPs at positions 1629 and 1640. Accordingly, benefit of the prior-filed application has not been granted, and the instant application filing date of October 17, 2003 has been used for prior art purposes.

### *Specification*

The disclosure is objected to because of the following informalities: The Sequence Listing filed with the instant application contains a single sequence – SEQ ID No: 1. The specification describes two primer sequences designated SEQ ID Nos: 1 and 2. These primer sequences appear to correspond to SEQ ID Nos: 3 and 4, respectively, of the parent case 10/102,731. It is suggested that the identifier used for the instant primer sequences be made consistent with the parent application to avoid confusion.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Saxena et al.

(Journal of Allergy and Clinical Immunology, May 2003; cited in IDS).

The instant claims are drawn to a method of detecting a predisposition to allergic bronchopulmonary aspergillosis (ABPA) based on the frequency of SNPs at positions 1649 and 1660 in exon 4 of the human SP-A2 gene.

Regarding claim 1, Saxena teaches a method of detecting a predisposition to allergic bronchopulmonary aspergillosis, comprising:

(a) designing primers capable of amplifying exon 4 of the human SP-A2 gene (Table 1 and page 1002, “polymerase chain reaction” section).

(b) amplifying genomic DNA of allergic bronchopulmonary aspergillosis patients and normal control subjects using the primers of step (a) (page 1002, Methods section)

(c) sequencing the amplified genomic DNA and identifying sequence variations computationally by comparing with an existing sequence of human SP-A2 DNA (page 1002 “Purification of PCR products and sequencing” section)

(d) screening normal control subjects and allergic bronchopulmonary aspergillosis patients for SNPs using the primers of step (a) (page 1002 “Purification of PCR products and sequencing” section)

(e) computing the frequency of G/C haplotypes at position 1649 and A/G haplotypes at position 1660 of the allergic bronchopulmonary aspergillosis and normal control subjects (page 1002 “Statistical analysis” section; see also Figure 1)

(f) establishing the association of G (at position 1649) and G (at position 1660) haplotypes with allergic bronchopulmonary aspergillosis disease based on their frequency distribution in the normal and afflicted patients (page 1003, column 2)

(g) predicting the risk or susceptibility to allergic bronchopulmonary aspergillosis based on the haplotype present at the polymorphic sites in the test subjects, where C at position 1649 and A at position 1660 is low risk and G at both position 1649 and 1660 is high risk (page 1003, column 2).

Regarding claims 2 and 3, Saxena teaches primers that correspond exactly to the instantly claimed primers for amplification of exon 4 of the human SP-A2 gene (see Table 1, primers 5 and 8). These primers are 30 nucleotides in length.

Regarding claim 4, Saxena teaches that the SP-A2 gene has allele variants which have G/C and A/G haplotypes (see abstract).

### ***Conclusion***

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Madan et al. (Clin. Chem. Lab Med. 2002) teach a method for determining a subject's predisposition to pulmonary tuberculosis based on the frequency of SNPs at position 1649 and 1660 of exon 4 of the SP-A2 gene (see abstract). Madan used primers corresponding exactly to

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the instant SEQ ID Nos: 1 and 2 for amplification (see Table 1, page 1004). However, neither Madan nor the prior art teaches or suggests application of the method to allergic bronchopulmonary aspergillosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner  
Art Unit 1637

amb



JEFFREY FREDMAN  
PRIMARY EXAMINER

C/7/06